

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluating efficacy and safety of sofosbuvir/ ledipasvir in treatment of COVID-19

Protocol summary

Study aim

Evaluating efficacy and safety of sofosbuvir/ledipasvir in treatment of COVID-19

Design

This is an open-label, randomized clinical trial to assess efficacy and safety (phase 2-3) of sofosbuvir/ledipasvir in treatment of COVID-19. Fifty eligible patients will be assigned to intervention or control group according to the permuted block randomization.

Settings and conduct

After introduction of the study protocol for patients admitted to Imam Khomeini Hospital, Tehran, Iran, and recording consent form, eligible patients will be recruited. Patients will be assigned to the intervention or the control group. Concomitant with the recommended national committee regimen, patients in the intervention group will receive sofosbuvir/ledipasvir 400/90 mg daily for 10 days. The control group will only receive the recommended national committee regimen. During the study period, patients will be monitored for response to the treatment and complications.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-75 years old persons with highly suspected or confirmed COVID-19 Exclusion criteria: History of drug allergy, pregnancy and lactation

Intervention groups

Included patients will assign to intervention or control group according to the permuted block randomization. Concomitant with the national proposed combination, the intervention group will receive one tablet of Sofosbuvir/ledipasvir 400/90 mg daily for 10 days. Patients in the control group will receive only the national proposed combination. Patients will be followed every daily for response to the treatment and adverse reactions up to the end of treatment.

Main outcome variables

Primary endpoints of the study are rates of treatment response and adverse drug reactions. Secondary endpoints are duration of hospitalization and patients'

clinical outcomes.

General information

Reason for update

Edition of the interventions due to changes in the national protocol

Acronym

IRCT registration information

IRCT registration number: **IRCT20100228003449N29**

Registration date: **2020-03-19, 1398/12/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-25, 1399/01/06**

Update count: **1**

Registration date

2020-03-19, 1398/12/29

Registrant information

Name

Hossein Khalili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4715

Email address

khalilih@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-18, 1398/12/28

Expected recruitment end date

2020-05-17, 1399/02/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating efficacy and safety of sofosbuvir/ ledipasvir in treatment of COVID-19

Public title

Effect of sofosbuvir/ ledipasvir on COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with highly suspected diagnosis of COVID-19
Patients with confirmed diagnosis of COVID-19
Patients who are candid for hospitalization
Patients who are candid for starting triple-drug combination

Exclusion criteria:

History of drug allergy
Pregnancy
Lactation

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done according to the blocks randomization method. Regarding to the sample size, 5 patients will be include in each block. SAS procedure PROC PLAN will be applied to generate the randomization schedule. This is a non-blinded randomized clinical trial.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University Of Medical Sciences

Street address

Ghods Ave. Tehran University of Medical Sciences,

Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417614411

Approval date

2020-03-17, 1398/12/27

Ethics committee reference number

IR.TUMS.VCR.REC.1398.1074

Health conditions studied**1****Description of health condition studied**

COVID-19 pneumonia

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Response to the treatment (improvement of patients' chief complaint, abnormal paraclinic and radiologic findings)

Timepoint

Daily

Method of measurement

According the clinical, paraclinical and laboratory findings

2**Description**

Gastrointestinal complications

Timepoint

Daily

Method of measurement

Interview and patient's record

3**Description**

Cutaneous complications

Timepoint

Daily

Method of measurement

Interview and patient's record

4**Description**

Neurological complications

Timepoint

Daily

Method of measurement

Interview and patient's record

5

Description

Renal complications

Timepoint

Daily

Method of measurement

Interview and patient's record

6

Description

Hematological complications

Timepoint

Daily

Method of measurement

Interview and patient's record

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

End of the treatment

Method of measurement

Patient's record

2

Description

Clinical outcome (cure or death)

Timepoint

End of treatment

Method of measurement

Patient's record

Intervention groups

1

Description

Intervention group: Concomitant with the national corona treatment recommendation (Tab hydroxychloroquine 400 mg twice daily at day 1 then 200 mg twice daily plus Tab lopinavir/ritonavir 200/50 mg two tablets twice daily for at least 5 days), patients will receive one tablet of sofosbuvir/ledipasvir 400/100 mg (Danesh Pharmaceutical Development Company) daily for 10 days.

Category

Treatment - Drugs

2

Description

Control group: Patients will receive the national corona treatment recommendation (Tab hydroxychloroquine 400 mg twice daily at day 1 then 200 mg twice daily plus Tab lopinavir/ritonavir 200/50 mg two tablets twice daily for at least 5 days).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Hossein Khalili

Street address

Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6695 4715

Email

khalilih@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

02166706141

Phone

+98 21 8898 7381

Email

msahrai@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hossein Khalili

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6695 4715

Email

khalilih@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hossein Khalili

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6695 4715

Email

khalilih@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hossein Khalili

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6695 4715

Email

khalilih@tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Results of the study will be published. The study protocol and statistical analysis will be included in the manuscript

When the data will become available and for how long

One year after finishing the study, data will be published and will be available in databases

To whom data/document is available

After permission from the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes

Under which criteria data/document could be used

Other researchers are permitted to included the results

in their systematic reviews and metaanalysis

From where data/document is obtainable

For this you may ask Hossein Khalili through following information: Address: Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran Postal code: 1417614411 E-mail: khalilih@tums.ac.ir

What processes are involved for a request to access data/document

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks

Comments